FDA-Compliant Labeling Checklist for Medical Devices & IVDs

Label Content Requirements

- Device name, model, and intended use clearly stated
- Manufacturer, distributor, and contact information
- Expiration date, lot/serial number, sterility information and storage/ handling conditions
- UDI barcode and human-readable version applied where required
- Regulatory statements (FDA 510(k) cleared)

Packaging & IFU

- Instructions for use (paper or electronic) meet regional requirements
- Label is present on both primary and secondary packaging
- All symbols accompanied by a glossary
- Device configuration (Rx and OTC) and quantity for each of the packaged content clearly indicated for OTC devices

Design & Compliance Best Practices

- Label text is legible and uses appropriate contrast
- Translations reviewed for target markets
- Layout validated for readability and print quality
- Label review documented under QMS design control
- Markings required by applicable standards and for which a conformity has been declared, are accounted for

Regulatory References

- 21 CFR 801 (Labeling) and 21 CFR 830 (UDI Rule) reviewed
- ISO 15223-1, 20417, and cited
- Labeling validated as part of design transfer